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Claims

1. A formulation comprising olanzapine or a  
pamoate salt or solvate thereof as an active ingredient and  
5 one or more carriers selected from the group consisting of  
an oleaginous carrier or cholesterol microsphere carrier.

2. A formulation as claimed in Claim 1 wherein  
said formulation has a prolonged sustained release of  
10 greater than 7 days and a burst release of less than 15% of  
the active ingredient.

3. A formulation as claimed in Claim 1 wherein  
said carrier is oleagenous.

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4. A formulation of Claim 1 wherein said carrier  
is selected from the group consisting of PLURONICS,  
cellulosic, gums, polysaccharide gums, vegetable oils,  
refined fractionated oils, sucrose diacetate  
20 hexaisobutyrate, chitosan, lecithin, and POVIDONE.

5. A formulation as claimed in Claim 4 wherein  
said carrier is selected from the group consisting of  
PLURONICS, cellulosic gums, polysaccharide gums, vegetable  
25 oils, and refined fractionated oils.

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6. A formulation as claimed by Claim 2 wherein the formulation further comprises one or more pharmaceutically acceptable excipients.

5 7. A formulation as claimed by Claim 6 wherein the pharmaceutically acceptable excipient is selected from the group consisting of a gelling agent and an antihydration agent.

10 8. A formulation as claimed in Claim 7 comprising olanzapine pamoate monohydrate, MIGLYOL812 and white wax.

9. A formulation as claimed in Claim 1 wherein  
15 olanzapine is the substantially pure Form II polymorph having a typical x-ray powder diffraction pattern as represented by the following interplanar spacings:

d (Å)
10.2689
8.577
7.4721
7.125
6.1459
6.071
5.4849
5.2181
5.1251
4.9874
4.7665

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4.7158  
4.4787  
4.3307  
4.2294  
4.141  
3.9873  
3.7206  
3.5645  
3.5366  
3.3828  
3.2516  
3.134  
3.0848  
3.0638  
3.0111  
2.8739  
2.8102  
2.7217  
2.6432  
2.6007

10. A formulation as claimed in Claim 1 wherein the carrier is a cholesterol microparticle.

5 11. A formulation as claimed in Claim 10 wherein the microparticle is a microsphere.

12. A formulation as claimed in Claim 10 wherein the cholesterol is selected from the group consisting of  
10 cholesterol, cholesterol palmitate, cholesterol oleate, cholesterol stearate, and cholesterol hemisuccinate.

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13. A formulation as claimed in Claim 10 wherein  
the microspheres have a particle size of from 20 to 500 $\mu$ m.

14. A formulation as claimed in Claim 13 wherein  
5 the particle size is from 30 to 200 $\mu$ m.

15. A formulation as claimed in Claim 14 wherein  
the particle size is from 40 to 100 $\mu$ m.

10 16. A formulation as claimed in Claim 10 wherein  
the microspheres are administered in an oleaginous carrier.

17. A formulation as claimed in Claim 16 wherein  
the oleaginous carrier is selected from the group consisting  
15 of PLURONICS, cellulosic gums, polysaccharide gums,  
vegetable oils, and refined fractionated oils.

18. A formulation as claimed in Claim 1 for use  
as a depot dosage form.

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19. A formulation as claimed in Claim 1 for use  
as a fast acting intramuscular dosage form.

20. A formulation as claimed in Claim 1 wherein  
25 the active ingredient is selected from the group consisting

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of olanzapine, olanzapine dihydrate D, olanzapine pamoate,  
olanzapine pamoate dimethanolate, olanzapine pamoate  
monohydrate, olanzapine pamoate THF solvate, bis(olanzapine)  
pamoate acetone solvate, and bis(olanzapine) pamoate  
5 monohydrate.

21. A formulation as claimed in Claim 20 wherein  
the active ingredient is milled.

10 22. A formulation as claimed in Claim 21 wherein  
the particle size is from 20 to 60 $\mu$ m.

23. A formulation as claimed in Claim 22 wherein  
the particle size is from 5 to 20 $\mu$ m.

15 24. A formulation as claimed in Claim 23 wherein  
the milled particles are less than or equal to 5  $\mu$ m.

25. A formulation as claimed in Claim 20 wherein  
20 the active ingredient is olanzapine pamoate monohydrate  
having a typical x-ray powder diffraction pattern as  
represented by the following interplanar spacing:

<u>d-spacing</u>	<u>Intensity</u>
10.76	98
9.20	62
8.38	85
8.18	24
7.62	20

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6.67	18
6.56	18
6.51	20
6.44	20
6.11	26
5.88	22
5.64	15
5.38	100
4.90	11
4.72	12
4.64	17
4.48	18
4.35	23
4.29	31
4.24	32
4.09	71
4.02	84
3.98	73
3.81	23
3.62	14
3.52	30
3.39	11
3.25	12
2.90	15
2.85	13

26. A formulation as claimed in Claim 20 wherein  
the active ingredient is bis(olanzapine) monohydrate having  
5 a typical x-ray powder diffraction pattern as represented by  
the following interplanar spacing:

<u>d-spacing</u>	<u>Intensity</u>
15.77	26
10.44	23
9.64	24
9.31	13
8.27	23
8.17	14
8.13	14
7.84	27
7.81	30
7.41	60
7.12	40

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7.00	13
6.96	13
6.55	45
6.18	53
5.87	38
5.80	19
5.59	89
5.25	26
5.00	34
4.96	31
4.88	61
4.85	73
4.71	34
4.52	19
4.33	11
4.19	100
4.12	48
4.05	39
3.97	30
3.89	31
3.80	29
3.72	20
3.70	21
3.58	33
3.45	27
3.04	13
2.84	16

27. A compound which is an olanzapine pamoate salt or solvate thereof.

5

28. A compound as claimed in Claim 27 wherein the pamoate salt is olanzapine pamoate dimethanolate having a typical x-ray powder diffraction pattern as represented by the following interplanar spacing:

<u>d-spacing</u>	<u>Intensity</u>
11.17	73
9.37	17
8.73	40
8.29	23
7.77	14

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7.22	24
6.84	31
6.66	54
6.42	11
6.40	11
6.17	26
5.87	12
5.56	100
4.84	11
4.66	17
4.57	26
4.48	22
4.35	19
4.28	19
4.12	94
4.03	91
3.89	52
3.62	44
3.54	11
3.29	16
3.13	16

29. A compound as claimed in Claim 27 wherein the  
pamoate salt is olanzapine pamoate monohydrate having a  
5 typical x-ray powder diffraction pattern as represented by  
the following interplanar spacing:

<u>d-spacing</u>	<u>Intensity</u>
10.76	98
9.20	62
8.38	85
8.18	24
7.62	20
6.67	18
6.56	18
6.51	20
6.44	20
6.11	26
5.88	22
5.64	15
5.38	100
4.90	11
4.72	12
4.64	17
4.48	18



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4.35	23
4.29	31
4.24	32
4.09	71
4.02	84
3.98	73
3.81	23
3.62	14
3.52	30
3.39	11
3.25	12
2.90	15
2.85	13

30. A compound as claimed in Claim 27 wherein the pamoate salt is bis(olanzapine) pamoate acetone solvate having a typical x-ray powder diffraction pattern as  
5 represented by the following interplanar spacing:

<u>d-spacing</u>	<u>Intensity</u>
16.87	32
9.58	35
8.88	80
8.40	16
8.19	35
7.85	16
7.34	29
7.22	25
7.04	30
6.87	18
6.77	11
6.73	11
6.65	21
6.36	12
6.26	26
5.76	31
5.58	79
5.53	100
5.45	61
5.32	42
5.19	39
5.02	55
4.91	69
4.87	51
4.85	57
4.69	44
4.61	68

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4.44	23
4.34	14
4.18	17
4.07	36
3.99	28
3.93	65
3.81	23
3.78	24
3.77	20
3.65	23
3.59	28
3.45	13
3.32	19
3.25	26

31. A compound as claimed in Claim 27 wherein the pamoate salt is bis(olanzapine) pamoate monohydrate solvate having a typical x-ray powder diffraction pattern as
- 5 represented by the following interplanar spacing:

<u>d-spacing</u>	<u>Intensity</u>
15.77	26
10.44	23
9.64	24
9.31	13
8.27	23
8.17	14
8.13	14
7.84	27
7.81	30
7.41	60
7.12	40
7.00	13
6.96	13
6.55	45
6.18	53
5.87	38
5.80	19
5.59	89
5.25	26
5.00	34
4.96	31
4.88	61
4.85	73
4.71	34
4.52	19
4.33	11

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4.19	100
4.12	48
4.05	39
3.97	30
3.89	31
3.80	29
3.72	20
3.70	21
3.58	33
3.45	27
3.04	13
2.84	16

32. A compound as claimed in Claim 27 wherein the  
pamoate salt is olanzapine pamoate THF solvate having a  
typical x-ray powder diffraction pattern as represented by  
5 the following interplanar spacing:

<u>d-spacing</u>	<u>Intensity</u>
14.59	100
7.78	16
7.24	56
7.00	19
6.37	12
6.04	11
6.01	11
4.85	19
4.69	42
4.39	25
4.28	19
3.95	13
3.84	20

33. A method of treating an animal, including a  
human suffering from or susceptible to psychosis, acute  
10 mania or mild anxiety states which comprises administering a  
pharmaceutically effective amount of a compound of Claim 27,  
28, 29, 30, 31 or 32.